THE UNIFORM BIOLOGICAL MATERIAL TRANSFER AGREEMENT

I. <u>Definitions</u>:

- 1. **PROVIDER**: Organization providing the **ORIGINAL MATERIAL**. The name and address of this party will be specified in an implementing letter.
- 2. **PROVIDER SCIENTIST**: The name and address of this party will be specified in an implementing letter.
- 3. **RECIPIENT**: Organization receiving the **ORIGINAL MATERIAL**. The name and address of this party will be specified in an implementing letter.
- 4. **RECIPIENT SCIENTIST**: The name and address of this party will be specified in an implementing letter.
- 5. **ORIGINAL MATERIAL**: The description of the material being transferred will be specified in an implementing letter.
- 6. MATERIAL: ORIGINAL MATERIAL, PROGENY, and UNMODIFIED DERIVATIVES. The MATERIAL shall not include: (a) MODIFICATIONS, or (b) other substances created by the RECIPIENT through the use of the MATERIAL which are not MODIFICATIONS, PROGENY, or UNMODIFIED DERIVATIVES.
- 7. **PROGENY**: Unmodified descendant from the **MATERIAL**, such as virus from virus, cell from cell, or organism from organism.
- 8. UNMODIFIED DERIVATIVES: Substances created by the RECIPIENT which constitute an unmodified functional subunit or product expressed by the ORIGINAL MATERIAL. Some examples include: subclones of unmodified cell lines, purified or fractionated subsets of the ORIGINAL MATERIAL, proteins expressed by DNA/RNA supplied by the PROVIDER, or monoclonal antibodies secreted by a hybridoma cell line.
- 9. **MODIFICATIONS**: Substances created by the **RECIPIENT** which contain/incorporate the **MATERIAL**.
- 10. **COMMERCIAL PURPOSES:** The sale, lease, license, or other transfer of the **MATERIAL** or **MODIFICATIONS** to a for-profit organization. **COMMERCIAL PURPOSES** shall also include uses of the **MATERIAL** or **MODIFICATIONS** by any

organization, including **RECIPIENT**, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the **MATERIAL** or **MODIFICATIONS** to a for-profit organization. However, industrially sponsored academic research shall not be considered a use of the **MATERIAL** or **MODIFICATIONS** for **COMMERCIAL PURPOSES** <u>per</u> <u>se</u>, unless any of the above conditions of this definition are met.

11. **NONPROFIT ORGANIZATION(S):** A university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute. As used herein, the term also includes government agencies.

II. Terms and Conditions of this Agreement:

- 1. The **PROVIDER** retains ownership of the **MATERIAL**, including any **MATERIAL** contained or incorporated in **MODIFICATIONS**.
- 2. The **RECIPIENT** retains ownership of: (a) **MODIFICATIONS** (except that, the **PROVIDER** retains ownership rights to the **MATERIAL** included therein), and (b) those substances created through the use of the **MATERIAL** or **MODIFICATIONS**, but which are not **PROGENY**, **UNMODIFIED DERIVATIVES** or **MODIFICATIONS** (i.e., do not contain the **ORIGINAL MATERIAL**, **PROGENY**, **UNMODIFIED DERIVATIVES**). If either 2 (a) or 2 (b) results from the collaborative efforts of the **PROVIDER** and the **RECIPIENT**, joint ownership may be negotiated.
- 3. The **RECIPIENT** and the **RECIPIENT SCIENTIST** agree that the **MATERIAL**:
- (a) is to be used solely for teaching and academic research purposes;
- (b) will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of the **PROVIDER**;
- (c) is to be used only at the **RECIPIENT** organization and only in the **RECIPIENT SCIENTIST**'s laboratory under the direction of the **RECIPIENT SCIENTIST** or others working under his/her direct supervision; and
- (d) will not be transferred to anyone else within the **RECIPIENT** organization without the prior written consent of the **PROVIDER**.

- 4. The **RECIPIENT** and the **RECIPIENT SCIENTIST** agree to refer to the **PROVIDER** any request for the **MATERIAL** from anyone other than those persons working under the **RECIPIENT SCIENTIST**s direct supervision. To the extent supplies are available, the **PROVIDER** or the **PROVIDER SCIENTIST** agrees to make the **MATERIAL** available, under a separate implementing letter to this Agreement or other agreement having terms consistent with the terms of this Agreement, to other scientists (at least those at **NONPROFIT ORGANIZATION(S)**) who wish to replicate the **RECIPIENT SCIENTIST**'s research; provided that such other scientists reimburse the **PROVIDER** for any costs relating to the preparation and distribution of the **MATERIAL**.
- 5. (a) The **RECIPIENT** and/or the **RECIPIENT SCIENTIST** shall have the right, without restriction, to distribute substances created by the **RECIPIENT** through the use of the **ORIGINAL MATERIAL** only if those substances are not **PROGENY**, **UNMODIFIED DERIVATIVES**, or **MODIFICATIONS**.
- (b) Under a separate implementing letter to this Agreement (or an agreement at least as protective of the **PROVIDER**'s rights), the **RECIPIENT** may distribute **MODIFICATIONS** to **NONPROFIT ORGANIZATION(S)** for research and teaching purposes only.
- (c) Without written consent from the **PROVIDER**, the **RECIPIENT** and/or the **RECIPIENT SCIENTIST** may NOT provide **MODIFICATIONS** for **COMMERCIAL PURPOSES**. It is recognized by the **RECIPIENT** that such **COMMERCIAL PURPOSES** may require a commercial license from the **PROVIDER** and the **PROVIDER** has no obligation to grant a commercial license to its ownership interest in the **MATERIAL** incorporated in the **MODIFICATIONS**. Nothing in this paragraph, however, shall prevent the **RECIPIENT** from granting commercial licenses under the **RECIPIENT**'s intellectual property rights claiming such **MODIFICATIONS**, or methods of their manufacture or their use.
- 6. The **RECIPIENT** acknowledges that the **MATERIAL** is or may be the subject of a patent application. Except as provided in this Agreement, no express or implied licenses or other rights are provided to the **RECIPIENT** under any patents, patent applications, trade secrets or other proprietary rights of the **PROVIDER**, including any altered forms of the **MATERIAL** made by the **PROVIDER**. In particular, no express or implied licenses or other rights are provided to use the **MATERIAL**, **MODIFICATIONS**, or any related patents of the **PROVIDER** for **COMMERCIAL PURPOSES**.
- 7. If the **RECIPIENT** desires to use or license the **MATERIAL** or **MODIFICATIONS** for **COMMERCIAL PURPOSES**, the **RECIPIENT** agrees, in advance of such use, to negotiate in good faith with the **PROVIDER** to establish the terms of a commercial license. It is understood by the **RECIPIENT** that the **PROVIDER** shall have no obligation to grant such a license to the **RECIPIENT**, and may grant exclusive or non-

exclusive commercial licenses to others, or sell or assign all or part of the rights in the **MATERIAL** to any third party(ies), subject to any pre-existing rights held by others and obligations to the Federal Government.

- 8. The **RECIPIENT** is free to file patent application(s) claiming inventions made by the **RECIPIENT** through the use of the **MATERIAL** but agrees to notify the **PROVIDER** upon filing a patent application claiming **MODIFICATIONS** or method(s) of manufacture or use(s) of the **MATERIAL**.
- 9. Any **MATERIAL** delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. The **PROVIDER** MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE **MATERIAL** WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.
- 10. Except to the extent prohibited by law, the **RECIPIENT** assumes all liability for damages which may arise from its use, storage or disposal of the **MATERIAL**. The **PROVIDER** will not be liable to the **RECIPIENT** for any loss, claim or demand made by the **RECIPIENT**, or made against the **RECIPIENT** by any other party, due to or arising from the use of the **MATERIAL** by the **RECIPIENT**, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the **PROVIDER**.
- 11. This agreement shall not be interpreted to prevent or delay publication of research findings resulting from the use of the **MATERIAL** or the **MODIFICATIONS**. The **RECIPIENT SCIENTIST** agrees to provide appropriate acknowledgment of the source of the **MATERIAL** in all publications.
- 12. The **RECIPIENT** agrees to use the **MATERIAL** in compliance with all applicable statutes and regulations, including Public Health Service and National Institutes of Health regulations and guidelines such as, for example, those relating to research involving the use of animals or recombinant DNA.
- 13. This Agreement will terminate on the earliest of the following dates: (a) when the **MATERIAL** becomes generally available from third parties, for example, through reagent catalogs or public depositories, or (b) on completion of the **RECIPIENT**'s current research with the **MATERIAL**, or (c) on thirty (30) days written notice by either party to the other, or (d) on the date specified in an implementing letter, provided that:
- (i) if termination should occur under 13(a), the **RECIPIENT** shall be bound to the **PROVIDER** by the least restrictive terms applicable to the **MATERIAL** obtained from

the then-available sources; and

RECIPIENT ORGANIZATION

- (ii) if termination should occur under 13(b) or (d) above, the **RECIPIENT** will discontinue its use of the **MATERIAL** and will, upon direction of the **PROVIDER**, return or destroy any remaining **MATERIAL**. The **RECIPIENT**, at its discretion, will also either destroy the **MODIFICATIONS** or remain bound by the terms of this agreement as they apply to **MODIFICATIONS**; and
- (iii) in the event the **PROVIDER** terminates this Agreement under 13(c) other than for breach of this Agreement or for cause such as an imminent health risk or patent infringement, the **PROVIDER** will defer the effective date of termination for a period of up to one year, upon request from the **RECIPIENT**, to permit completion of research in progress. Upon the effective date of termination, or if requested, the deferred effective date of termination, **RECIPIENT** will discontinue its use of the **MATERIAL** and will, upon direction of the **PROVIDER**, return or destroy any remaining **MATERIAL**. The **RECIPIENT**, at its discretion, will also either destroy the **MODIFICATIONS** or remain bound by the terms of this agreement as they apply to **MODIFICATIONS**.
 - 1. Paragraphs 6, 9, and 10 shall survive termination.
 - 1. The **MATERIAL** is provided at no cost, or with an optional transmittal fee solely to reimburse the **PROVIDER** for its preparation and distribution costs. If a fee is requested by the **PROVIDER**, the amount will be indicated in an implementing letter.

IDENTIFYING INFORMATION AND APPROVAL SIGNATURES

Recipient Investigator/Scientist:	
	(Name)
	(Title)
	(Full Address)

	
(Telephone number)	(FAX number)
Signature:	
Date:	
Recipient Authorization:	
(Representative authorized by the Recipient to appro	ove this agreement)
	(Name)
	(Title)
	(Full Address)
(Telephone number)	(FAX number)
Signature:	-
Date:	
PROVIDER ORGANIZATION	
Provider Investigator/Scientist:	
	(Name)
	(Title)
	(Full Address)

	
(Telephone number)	(FAX number)
Signature:	
Date:	
Provider Authorization:	
(Representative authorized by the Provider to approve	e this agreement)
	(Name)
	(Title)
	(Full Address)
	·
(Telephone number)	(FAX number)
Signature:	
Date:	
*SPECIAL NOTE RE AUTHORIZING SIGNATUR	ES: Use the following information for the
appropriate NIEHS Authorizing Signature block, depo	endent upon whether or not NIEHS is the
Provider or the Recipient:	
Dr. John S. Penta	
NIEHS Technology Transfer Coordinator	
Office of Clinical Research	
MD A2-05, Room A231, South Campus	

P. O. Box 12233

Research Triangle Park, NC 27709

TELEPHONE: (919) 541-3696 and FAX: (919) 541-2260